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Ex Parte Odidi et al.
Application No. 09/845,497
Docket No. 9577-25 LAB

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Applicant	:	ODIDI, Amina, et al.
Filed:	:	May 1, 2001
TC/Art Unit	:	1616
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Docket No.	:	9577-25 LAB
Title	:	EXTENDED RELEASE PHARMACEUTICALS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria VA 22313-1450

APPEAL BRIEF

Sir:

Further to the Notice of Appeal filed March 2, 2010, the Appellants present this Appeal Brief, and respectfully requests that this appeal be considered by the Board of Patent Appeals and Interferences.

The Appellants submit herewith the required fee of $270.00 for payment of the official fee for the Appeal Brief.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. **192253**, referencing docket number **9577-25 LAB**.

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This is an Appeal from the decision of the Examiner finally rejecting claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34 of the above identified application.

I. REAL PARTY IN INTEREST

The above identified application is assigned to IntelliPharmaCeutics Corp., 30 Worcester Road, Toronto, Ontario CA M9W 5X2, which is the real party in interest. An Assignment has been recorded in the Office at Reel 013751, Frame 0380 on 02/11/2003.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences or other judicial proceedings related to the instant application.

III. STATUS OF CLAIMS

A. Total Number of Claims in the Application

There were originally 32 claims pending in this application, numbered as 1 to 32.

B. Status of All Claims

1. Claims cancelled: 12 claims cancelled, Claims 2 – 5, 10, 12 – 14, 18 – 20, and 33.
2. Claims withdrawn but not cancelled: None.
3. Claims pending: 22; Claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34.
4. Claims allowed: None.
5. Claims objected to: None.
6. Claims rejected: 22; Claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34.

C. Claims on Appeal

The claims on appeal are Claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34.

IV. STATUS OF AMENDMENTS

The claims were last amended with arguments on the merits on May 22, 2008 in an Amendment and Response to the Office Action of February 7, 2008;

the Amendment was entered. Two Office Actions subsequently were issued, each being answered with a Response without further amendment of the claims.

On April 1, 2010, an additional Amendment was filed under 37 CFR 1.116 to correct a minor typographical error in the specification, and to present the rejected claims in better form for consideration on appeal.

The current status of the claims is shown in the Claims Appendix provided in Section VIII herein. The status of each claim is provided with the presumption that the Amendment of April 1, 2010 has been entered. This Appeal from the decision of the Examiner is responsive to a third and most recent Office Action issued September 9, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites an extended release pharmaceutical active formulation comprising a capsule, tablet or pellet encased by an encasement coat, wherein the formulation provides over 12 hours of extended release of the pharmaceutical active in the bloodstream.

The capsule, tablet, pellet, or bead comprises about 5-95% by weight pharmaceutical active and an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar. Teaching of the 5-95% pharmaceutical active is found in the specification at page 3, paragraph 17, lines 2 – 3, and at page 4, paragraph 38, lines 4 – 5. Teaching of the pharmaceutical compression aid and the pharmaceutical extrusion aid is found in the specification at page 4, paragraph 38, lines 6 – 10.

The encasement coat comprises one or more layers of a polymeric film encasing said capsule, tablet or pellet, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol. Teaching of the encasement coat is found in the

specification at pages 2 – 3, paragraph 15, lines 2 – 4; and at page 3, paragraph 36, lines 6 – 8; and at page 4, paragraph 39, lines 1 – 2.

Teaching of the 12 hours of extended release of the pharmaceutical active in the bloodstream is found in the specification at page 3, paragraph 37.

Dependent claim 6, depending upon claim 1, recites that compression aid is present in an amount of up to about 60% by weight. Teaching of this feature in the specification is found at page 3, paragraph 17, lines 3 – 4, and at page 4, paragraph 38, line 5.

Dependent claim 7, depending upon claim 1, recites that extrusion aid is present in an amount of up to about 50% by weight. Teaching of this feature is found in the specification at page 3, paragraph 17, lines 4 – 5, and at page 4, paragraph 38, lines 5 – 6.

Dependent claim 8, depending upon claim 1, recites that the formulation of claim 1 additionally comprises excipients, lubricants, binders or glidants. Teaching of this feature is found in the specification at page 4, paragraph 38, lines 10 – 11.

Dependent claim 9, depending upon claim 1, recites that the polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof. Teaching of this feature is found in the specification at page 4, paragraph 39, lines 2 – 5.

Dependent claim 11, depending upon claim 1, recites that the polymeric film comprises shellac or zein. Teaching of this feature is found in the specification at page 4, paragraph 39, lines 5 – 6.

Dependent claim 15, depending upon claim 1, recites that the pharmaceutical active is selected from the group consisting of risedronate, alendronate, riluzole, and sulfonylureas. Teaching of this feature is found in the specification at page 5, paragraph 42, lines 1 – 2.

Dependent claim 22, depending upon claim 15, recites that the polymeric film further comprises an agent selected from the group consisting of plasticizers,

antitacking agents, colorants and mixtures thereof. Teaching of this feature in the specification is found at page 4, paragraph 41, lines 6 – 7.

Dependent claim 27, depending upon claim 15, recites that the release of the pharmaceutical active exhibits a lag phase (time) and after which release is extended over 12 hours or 24 hours after administration. Teaching of this feature is found in the specification at page 2, paragraph 14, and at page 3, paragraph 37.

Dependent claim 16, depending upon claim 1, recites that the pharmaceutical active is selected from the group consisting of bioactive peptides, antitumor agents, antibiotics, antipyretic analgesic antiinflammatory agents, antitussive expectorants, sedatives, muscle relaxants, antiepileptics, antiulcer agents, antidepressants, anti-allergic agents, cardiotonics, antiarrhythmic agents, vasodilators, hypotensive diuretics, anticoagulants, hemolytics, antituberculosis agents, hormones, narcotic antagonists, bone resorption suppressors and angiogenesis suppressors. Teaching of this feature is found in the specification at page 5, paragraph 43, lines 2 – 7.

Dependent claim 24, depending upon claim 1, further recites that greater than 80% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C. Teaching of this feature is found in the specification at page 7, paragraph 54, and the table therebeneath, and with reference on page 8, paragraph 57, to United States Pharmacopeia National Formulary standard USP 23 NF 18 (pp. 1791 – 1792 in particular), which describes a standardized procedure for dissolution testing of capsules or tablets. (N.B.: The specification was amended on April 1, 2010 to correct a minor typographical error, such that the standard properly reads, "USP 23 NF 18.")

Dependent claim 25, depending upon claim 1, further recites that less than about 20% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and greater than 80% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated

intestinal fluid (pH 7.5 phosphate buffer) and 37°C. Teaching of this feature is found in the specification at page 8, Example 1(e).

Dependent claim 26, depending upon claim 1, recites that the tablet or pellet is made by direct compression. Teaching of this feature is found in the specification at page 3, paragraph 36, lines 4 – 5 and at page 4, paragraph 40, lines 1 – 3.

Dependent claim 28, depending upon claim 1, recites that the capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 24 hours when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C. Teaching of this feature is found in the specification at page 2, paragraph [7], line 3; and at page 3, paragraph [37], line 2; and with reference on page 8, paragraph 57, to United States Pharmacopeia National Formulary standard USP 23 NF 18 (pp. 1791 – 1792 in particular), which describes a standardized procedure for dissolution testing of capsules or tablets.

Dependent claim 29, depending upon claim 1, recites that the capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 24 hours when tested in a USP apparatus at 75 rpm in 900mls simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and demonstrates extended release characteristics of greater than 24 hours when tested in a USP apparatus at 75 rpm in 900mls simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C. Teaching of this feature is found in the specification at page 2, paragraph [7], line 3; and at page 3, paragraph [37], line 2; and with reference on page 8, paragraph 57, to United States Pharmacopeia National Formulary standard USP 23 NF 18. (See preceding paragraph.)

Dependent claim 34, depending upon claim 1, recites that the pharmaceutical active is selected from the group consisting of glyburide, chlorpropamide, tolbutamide, glimepiride, acarbose, alglucerase, miglitol, nateglinide, pimagidine, pioglitazone, pramlintide, repaglinide, rosiglitazone, troglitazone, hypoglycemic benzenesulfonamido pyrimidines, buformin and phenformin. Teaching of this feature is found in the specification at page 5, paragraph 42, lines 3 – 7.

Independent claim 17 recites an extended release pharmaceutical active formulation comprising a capsule, tablet or pellet or bead encased by an encasement coat, wherein the formulation provides over 12 hours of extended release of the pharmaceutical active in the bloodstream.

The capsule, tablet, pellet, or bead comprises about 5-95% by weight pharmaceutical active, about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar, and about 0-50% by weight pharmaceutical extrusion aid. Teaching of this subject matter is found in the specification at page 4, paragraph 38.

The encasement coat comprises one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight polyethylene glycol. Teaching of the encasement coat is found in the specification at page 4, paragraph 39; and at page 7, Example 1(c) Table row 3 and paragraph 55.

Teaching of the 12 hours of extended release of the pharmaceutical active in the bloodstream is found in the specification at page 3, paragraph 37.

Dependent claim 21, depending upon claim 17, recites that the polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof. Teaching of this feature is found in the specification at page 4, paragraph 39, lines 2 – 5.

Dependent claim 30, depending upon claim 21, further recites that the pharmaceutical active release exhibits a lag phase (time) after which release is extended over 12 hours or 24 hours when administered to humans or animals in the presence of food. Teaching of this feature is found in the specification at page 3, paragraph 37.

Independent claim 23 recites an extended release pharmaceutical active formulation comprising a capsule, tablet, pellet, or bead comprising about 5-95% by weight pharmaceutical active; about 0-60% by weight pharmaceutical compression aid; about 0-50% by weight pharmaceutical extrusion aid; and an encasement coat, wherein the formulation provides over 12 hours of extended release of the pharmaceutical active in the bloodstream. The encasement coat comprises one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol.

Teaching of the 5-95% pharmaceutical active is found in the specification at page 3, paragraph 17, lines 2 – 3, and at page 4, paragraph 38, lines 4 – 5. Teaching of the 0-60% pharmaceutical compression aid is found in the specification at page 3, paragraph 17, lines 3 – 4, and at page 4, paragraph 38, line 5. Teaching of the 0-50% by weight pharmaceutical extrusion aid is found in the specification at page 3, paragraph 17, lines 4 – 5, and at page 4, paragraph 38, lines 5 – 6. Teaching of the encasement coat is found in the specification at page 4, paragraph 39; and at page 7, Example 1(c) Table row 3 and paragraph 55.

Independent claim 31 recites method for making an extended release pharmaceutical active formulation comprising compressing about 5-95% by weight pharmaceutical active into a capsule, tablet, pellet, or bead, and encasing them in an encasement coat, wherein the formulation provides over 12 hours of extended release of said active in the bloodstream. A teaching of the overall method is found in the specification at page 3, paragraph 18; and at page 4, paragraphs 39 – 40; and on pp. 6 – 7, Examples 1(a), 1(c), and 1(d).

The capsules, etc. are compressed with an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate,

calcium sulfite dihydrate, tricalcium phosphate and compressible sugar. Teaching of these features is found in the specification at page 4, paragraph 38.

The encasement coat comprises one or more layers of a polymeric film, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol. Teaching of the encasement coat is found in the specification at page 4, paragraph 39; and at page 7, Example 1(c) Table row 3 and paragraph 55.

Teaching of the 12 hours of extended release of the pharmaceutical active in the bloodstream is found in the specification at page 3, paragraph 37.

Dependent claim 32, depending upon claim 31, recites that the pharmaceutical compression aid is present in an amount of up to about 60% by weight and the pharmaceutical extrusion aid is present in an amount of up to about 50% by weight. Teaching of this feature is found in the specification at page 3, paragraph 17, lines 3 – 5, and at page 4, paragraph 38, lines 5 – 6.

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

Whether claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34 are properly rejected under 35 USC 103(a) as obvious over U.S. Pat. No. 6,106,864 of Dolan et al. in view of U.S. Pat. No. 5,800,422 of Dong et al., and in view of U.S. Pat. No. 6,099,859 of Cheng.

VII. ARGUMENT

For the purposes of this appeal only, the Appellants accept without prejudice the presumption that all dependent claims stand or fall together in view of these claims depending from independent claims 1, 17, 23, or 31.

Regarding the rejection of claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34 under 35 USC 103(a) as obvious over U.S. Pat. No. 6,106,864 of Dolan et al. in view of U.S. Pat. No. 5,800,422 of Dong et al., and in view of U.S. Pat. No. 6,099,859 of Cheng:

The rejection under 35 USC 103(a) is improper because the cited prior art do not teach all of the features recited in the Appellants' respective independent claims 1, 17, 23, and 31.

The Office Action of September 9, 2009 asserts that Dolan teaches oral dosage forms of actives and teaches that a matrix comprising the active can be coated with an impermeable coating (see column 2, lines 53 – 57; see column 3, lines 1 – 7). The Office Action further asserts that the Appellants' recitation of an "encasement coat" can be construed as including an aperture. (See p.4, last four lines through p.5 first line of the Office Action.) It is respectfully submitted that these assertions are incorrect.

A. The Office has erred in its interpretation of the teachings of U.S. Pat. No. 6,106,864 of Dolan et al. ("Dolan"). The term "encasement coat" as recited in independent claims 1, 17, 23, and 31 should not be construed as possibly including an aperture as taught by Dolan.

The Examiner states at page 4, paragraph 2 of the Office action as follows:

> "Applicants argue that instant encasement coat has no aperture like Dolan's coat. The examiner argues that the instant encasement coat having no aperture is not recited in the claim and therefore no patentable weight is given to the instant encasement coat having no aperture. In addition, the instant claims employ comprising language which allows for the inclusion of an aperture in the instant encasement coat."

It is respectfully submitted that it is improper to assert that the Appellants' term "encasement coat" could include an aperture. The Appellants recognize that in accordance with MPEP § 2111, during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." However, the Office is to determine the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

And from *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification."

Additionally, "The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)

The Appellants' meaning of the term "encasement coat" is very clear from their specification. Paragraph [13] on page 2 of the specification reads as follows:

> "It is a further object of the present invention to provide an extended and controlled release composition and formulation of pharmaceuticals that is ***not*** *a controlled release pharmaceutical tablet comprising a core containing the pharmaceuticals, a semipermeable coating membrane surrounding the core* ***with passageway(s) in the membrane***." (Emphasis added.)

And in paragraph [36] on page 3:

> "...the pharmaceutical active tablet is encased in one or more layers of pH solubility dependant polymeric film(s) which is not semipermeable, non permeable, non swellable and ***has no passage way***." (Emphasis added.)

Clearly, the broadest reasonable construction of the term "encasement coat" in independent claims 1, 17, 23, and 31 in light of these disclosures, as would be interpreted by one of ordinary skill in the art would be that the encasement coat is a continuous coat surrounding the tablet, pellet, capsule, or bead which does not include passageways, i.e., apertures.

Additionally, it has been held that, "during examination the USPTO must give claims their broadest reasonable interpretation in light of the specification. This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)

And "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) (*en banc*).

With regard to the plain meaning of the terms "encasement" and "encasing," which are recited in independent claims 1, 17, 23, and 31, *The American Heritage® Dictionary of the English Language*, Fourth Edition, © 2009 defines "encase" as follows: "To enclose in or as if in a case."

Cleary, the plain meaning of "encasement" and "encasing" does not include being contained within something that includes passageways or apertures therethrough. In the case of *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003), it was found that, "In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor." The meanings of "encasement" and "encasing" that are most consistent with the use of the words by the Appellants in their specification is that the encasement coat comprises a polymer film that does *not* include an aperture.

Additionally, the Examiner has referred to the Appellants' encasement coat in an equivalent term, reciting on page 2, paragraph 1 of the Office Action of March 26, 2007, "Applicant has amended claims to recite that it is the capsule, tablet, bead, or pellet which is *encapsulated* rather than to the *encapsulation* of only the active ingredient." (Emphasis added.)

Dictionary.com Unabridged, based upon on the *Random House Dictionary*, © Random House, Inc. 2010, defines the term "encapsulate" as follows: "to become enclosed in or as if in a capsule." "Capsule" is further defined as "a gelatinous case enclosing a dose of medicine." Ibid. The Appellants respectfully submit that the Examiner himself had interpreted the

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meaning of the terms "encasement" and "encasing" in a manner consistent with the Appellants' arguments above, prior to his raising the issue of these terms being construable to include an aperture.

For at least the foregoing reasons, it is respectfully submitted that the term "encasement coat" as recited in independent claims 1, 17, 23, and 31 cannot be construed as including an aperture as taught by Dolan.

B. The Office has erred in its assertion that Dolan teaches that the active ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) which are impermeable and soluble at pH greater than 5.

The Office Action asserts that Dolan teaches that ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers (see column 3, lines 7-38). (It has already been established that that ethyl cellulose is not a cellulose ester; as acknowledged in the Office Action of 9/9/2009).

It is respectfully submitted that Dolan's coat is either impermeable with an aperture, as noted in (c) at column 2, lines 42 – 44 and column 3, lines 11 – 21, or the coat can have low aqueous solubility (e.g. water soluble at pH >5), as noted in (d) at column 2, lines 46 – 47, and column 3, lines 22 – 30. Dolan teaches the use of non-enteric cellulose esters (soluble in the acidic pH range), such as cellulose acetate, in conjunction with an impermeable coat, as noted in (c) at column 3, lines 11 – 21, and with a semi-permeable coat, as noted in (e) at column 3, lines 32 – 37. Dolan does not teach or suggest an encasement coat, *as a whole*, being both non-permeable and soluble in a pH of above about 5.0, as recited in independent claims 1, 17, 23, and 31. Polyethylene glycol (PEG) is used in the coat of the claimed invention to achieve the non-permeability (e.g. not permeable; no drug goes through) of the coat that is soluble at a pH of above about 5.0. Therefore, the Office Action's assertion that "Dolan teaches that the active ingredients can be formulated into a tablet which can be coated

with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) which are impermeable and soluble at pH greater than 5 (Dolan column 3, lines 7 – 38)" is incorrect. Moreover, if the coating of Dolan is non-permeable, it would include an aperture and be non- enteric, as taught at Column 3, lines 15 – 18. Dolan does not teach or suggest a coat being both non-permeable and soluble in a pH of above about 5.0.

C. The Office has erred in its assertion that Dolan teaches oral dosage forms of actives and teaches that a matrix comprising the active can be coated with an impermeable coating. (Asserted with reference to column 2, lines 53-57; and column 3, lines 1-7).

To the contrary, it is respectfully submitted that Dolan teaches that the impermeable coating is non-enteric (as noted in the description at Column 3, lines 15 – 18 with respect to the examples provided) and must have an aperture (see column 3, lines 1 – 7 and lines 11 – 21), as has been established in the above arguments.

D. The Office has erred in its assertion that Dong teaches the use of PEG in a coating and that it would have been obvious to include PEG in the coating of Dolan.

To the contrary, it is respectfully submitted that the specific combination of the claimed invention (e.g. polymer and PEG) yields a coating that is both non-permeable and soluble in a pH of above about 5.0. Therefore, one skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat (e.g. non- permeable coat), since an impermeable coat of Dolan is associated with non-enteric coats, which dissolve at pH below 5.0; see Column 3, lines 15-18 of Dolan.

E. The Office has erred in its assertion that Cheng teaches that PEG is a flux-enhancing agent, which allows the drug to be released through the pores of the coat, and that it would therefore have been obvious to modify the invention

of Dolan to include the PEG to enhance the release of the drug through the pores.

To the contrary, it is respectfully submitted that as noted above, the PEG is used in the claimed invention to aid in making the coating non-permeable. Therefore, one skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat, since Cheng clearly teaches that PEG makes the coating permeable. (See Column 4, lines 28 – 38 of Cheng.)

For at least the foregoing reasons, the rejection of the Appellants' independent claims 1, 17, 21, and 31 under 35 USC 103(a) is improper because the cited prior art of Dolan, Dong and Cheng do not teach all of the features recited in these claims.

It is respectfully submitted that the failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103, despite any recent revision to the Manual of Patent Examining Procedure (MPEP). Section 2143.03 of the MPEP requires the "consideration" of every claim feature in an obviousness determination. To render a claim unpatentable, however, the Office must do more than merely "consider" each and every feature for this claim. Instead, the asserted combination of the patents to Dolan, Dong et al., and Cheng et al. must also teach or suggest *each and every claim feature*. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974): (emphasis added) ("to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art"). Indeed, as the Board of Patent Appeals and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." See *In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including

... ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Indeed, the Appellants respectfully submit that this is why Section 904 of the MPEP instructs Examiners to conduct an art search that covers "the invention *as described and claimed.*" (Emphasis added). Lastly, the Appellants respectfully direct attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the features of a claim, since the Supreme Court in *KSR Int'l v. Teleflex Inc.* stated that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (*quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

In summary, it remains well-settled law that a finding of obviousness requires at least a suggestion of all of the features in a claim. *See In re Wada and Murphy, citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

Reversal of the Examiner's rejection of these claims, as well as the rejections of dependent claims 6 – 9, 11, 15, 16, 22 – 30, 32, and 34 by the Board of Patent Appeals and Interferences is respectfully requested.

VIII. CLAIMS APPENDIX

The following is a listing of claims in the instant application. Claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34 are under appeal.

Claim 1 (Previously presented) An extended release pharmaceutical active formulation comprising:

- a capsule, tablet, pellet, or bead comprising about 5-95% by weight pharmaceutical active and an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet or pellet, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

Claim 2 (Cancelled).

Claim 3 (Cancelled).

Claim 4 (Cancelled).

Claim 5 (Cancelled).

Claim 6 (Previously presented) The formulation of claim 1, wherein said compression aid is present in an amount of up to about 60% by weight.

Claim 7 (Previously presented) The formulation of claim 1, wherein said extrusion aid is present in an amount of up to about 50% by weight.

Claim 8 (Previously presented) The formulation of claim 1, wherein said formulation additionally comprises excipients, lubricants, binders or glidants.

Claim 9 (Previously presented) The formulation of claim 1, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.

Claim 10 (Cancelled).

Claim 11 (Original) The formulation of claim 1, wherein said polymeric film comprises shellac or zein.

Claim 12 (Cancelled).

Claim 13 (Cancelled).

Claim 14 (Cancelled).

Claim 15 (Previously presented) The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of risedronate, alendronate, riluzole, and sulfonylureas.

Claim 16 (Original) The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of bioactive peptides, antitumor agents, antibiotics, antipyretic analgesic antiinflammatory agents, antitussive expectorants, sedatives, muscle relaxants, antiepileptics, antiulcer agents, antidepressants, anti-allergic agents, cardiotonics, antiarrhythmic agents, vasodilators, hypotensive diuretics, anticoagulants, hemolytics, antituberculosis agents, hormones, narcotic antagonists, bone resorption suppressors and angiogenesis suppressors.

Claim 17 (Previously presented) An extended release pharmaceutical active formulation comprising:

- a capsule, tablet, pellet or bead of about 5-95% by weight pharmaceutical active, about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar, and about 0-50% by weight pharmaceutical extrusion aid,

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

Claim 18 (Cancelled).

Claim 19 (Cancelled).

Claim 20 (Cancelled).

Claim 21 (Previously presented) The formulation of claim 17, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.

Claim 22 (Original) The formulation of claim 15, wherein said polymeric film further comprises an agent selected from the group consisting of plasticizers, antitacking agents, colorants and mixtures thereof.

Claim 23 (Previously presented) An extended release pharmaceutical active formulation comprising:

a capsule, tablet, pellet or bead of pharmaceutical active comprising;

- about 5-95% by weight pharmaceutical active;
- about 0-60% by weight pharmaceutical compression aid;
- about 0-50% by weight pharmaceutical extrusion aid; and
- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,
- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

Claim 24 (Previously presented) The formulation of claim 1, wherein greater than 80% of said pharmaceutical active is released in one hour when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C.

Claim 25 (Previously presented) The formulation of claim 1, wherein less than about 20% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and greater than 80% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

Claim 26 (Previously presented) The formulation of claim 1, wherein the tablet or pellet is made by direct compression.

Claim 27 (Original) The formulation of claim 15, wherein the release of the pharmaceutical active exhibits a lag phase (time) and after which release is extended over 12 hours or 24 hours after administration.

Claim 28 (Previously presented) The formulation of claim 1, wherein the capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 24 hours when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C.

Claim 29 (Previously presented) The formulation of claim 1, wherein said capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 24 hours when tested in a USP apparatus at 75 rpm in 900mls simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and demonstrates

extended release characteristics of greater than 24 hours when tested in a USP apparatus at 75 rpm in 900mls simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

Claim 30 (Original) The formulation of claim 21, wherein pharmaceutical active release exhibits a lag phase (time) after which release is extended over 12 hours or 24 hours when administered to humans or animals in the presence of food.

Claim 31 (Previously presented) A method for making an extended release pharmaceutical active formulation comprising:

- compressing about 5-95% by weight pharmaceutical active into a capsule, tablet, pellet or bead with an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- encasing said capsules, tablets, pellets or beads in an encasement coat comprising one or more layers of a polymeric film, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

Claim 32 (Previously presented) The method of claim 31, wherein said pharmaceutical compression aid is present in an amount of up to about 60% by weight and said pharmaceutical extrusion aid is present in an amount of up to about 50% by weight.

Claim 33 (Cancelled).

Claim 34 (Previously presented) The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of glyburide, chlorpropamide, tolbutamide, glimepiride, acarbose, alglucerase, miglitol, nateglinide, pimagidine, pioglitazone, pramlintide, repaglinide, rosiglitazone, troglitazone, hypoglycemic benzenesulfonamido pyrimidines, buformin and phenformin.

IX. EVIDENCE APPENDIX

There is no new evidence being introduced in this appeal.

X. RELATED PROCEEDINGS APPENDIX

There are no other proceedings related to the instant application.

XI. CONCLUSION

For the extensive reasons advanced above in Section VII, Arguments, the Appellants respectfully contend that each of claims 1, 6 – 9, 11, 15 – 17, 21 – 32, and 34 is patentable. Therefore, reversal of all rejections is courteously requested.

To the extent necessary, please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account number 192253 and credit any excess fees to such deposit account.

Respectfully submitted,

SIM & McBURNEY

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